

EXHIBIT 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC

Plaintiff,

v.

HETERO USA, INC., HETERO LABS LTD., and
HETERO LABS LTD. UNIT-VI

Defendants.

C.A. No. 1:24-cv-01025-JLH

**DEFENDANTS’ OBJECTIONS AND RESPONSES TO PLAINTIFF’S FIRST SET OF
REQUESTS FOR PRODUCTION (NOS. 1-41)**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (“Defendants” or “Hetero”) hereby object and respond to Plaintiff’s First Set of Requests for Production (the “Requests”). These objections and responses are based on Defendants’ current understanding, knowledge and belief. As the case is in its early stages, Defendants’ factual investigation and trial preparation are ongoing. Defendants reserve the right to supplement their responses as discovery progresses in this action and/or as new information becomes available.

GENERAL STATEMENT AND OBJECTIONS

Hetero asserts each of the following General Objections and expressly incorporates them into each response set forth below. By providing a specific response to any Request, Hetero does not waive or otherwise limit these General Objections. Furthermore, reference to any of these General Objections in any specific response shall not waive or otherwise limit the applicability of all these General Objections to each and every response.

1. Hetero objects to the Requests to the extent the Requests and/or the definitions and instructions contained or incorporated therein are unduly burdensome and oppressive, overly broad, vague, ambiguous and/or to the extent they are inconsistent with and/or seek to impose upon Hetero obligations beyond those required by the Federal Rules of Civil Procedure, the Local Rules for the United States District Court for the District of Delaware, or any order of the Court in this matter.

2. Hetero objects to the Requests to the extent the Requests and/or the definitions and instructions contained or incorporated therein seek documents or information not reasonably available to, or not within the possession, custody or control of Hetero. Such demands are beyond the scope of the Federal Rules of Civil Procedure. Any response given will therefore be based upon information and/or documents within Hetero's possession, custody or control. By stating in these responses that it will produce documents or things or is searching for documents or things, Hetero does not represent that any document(s) or thing(s) actually exists, but rather that it will make a diligent search and reasonable inquiry to ascertain whether documents or things responsive to the Requests do in fact exist.

3. Hetero has not completed its investigation of the facts relating to the present litigation. Hetero's responses to the Requests are therefore made to the best of Hetero's present knowledge, information and belief. These responses are at all times subject to such additional and/or different information that discovery and/or independent investigation or analysis may disclose. Hetero accordingly reserves the right to modify its responses or supplement its document production after it has substantially completed its investigation, and as additional facts are ascertained, analysis is made, legal research is completed, and contentions are made.

4. Hetero expressly reserves the right to amend and/or supplement its responses to the Requests after the claims have been construed by the Court, Plaintiff has disclosed its infringement contentions and claim construction positions, and discovery has been completed.

5. By agreeing to provide information responsive to a particular Request, Hetero does not admit the relevance or admissibility of the documents or information provided. Nothing contained in any responses herein shall be deemed an admission, concession, or waiver by Hetero as to the relevance, materiality, or admissibility of any document or thing provided in response to the Requests.

6. Hetero objects to the Requests to the extent they use language incorporating or calling for a legal conclusion or making an erroneous statement of law. Hetero's responses herein shall be as to matters of fact only and shall not be construed as stating or implying conclusions of law concerning the matters referenced in any Request.

7. Hetero objects to the Requests to the extent they prematurely and improperly seek discovery of expert opinions. Such information will be disclosed in accordance with the Court's Scheduling Order.

8. Hetero objects to the Requests to the extent they are not properly limited in subject matter, scope and/or time, employ vague, undefined or uncertain terms or phrases and/or call for investigations or activities the costs or burdens of which are unreasonable under the circumstances.

9. Hetero objects to the Requests to the extent they call for any document or thing protected by the attorney-client privilege, the attorney work-product doctrine or any other applicable doctrine, privilege or immunity, including without limitation, consulting expert privileges, or prepared in anticipation of litigation, such that it would make the information immune or exempt from discovery. As an example, and without limiting this general objection in

any way, Hetero objects to each and every Request that seeks “all documents” that “refer or relate” or “referring or relating to” or “concerning” a particular topic to the extent such Requests call for the production of information protected by the attorney-client privilege, the attorney work-product doctrine, or any other applicable doctrine. The inadvertent disclosure of any such information shall not signify any intent by Hetero to waive such privilege, protection, or immunity. Inadvertent production of any document that is subject to such privilege, protection, or immunity in response to any of the Requests shall not constitute or be deemed to constitute a waiver of such privilege, protection or immunity.

10. Hetero objects to the Requests to the extent they seek documents or information that are already in the possession, custody, or control of Plaintiff or Plaintiff’s counsel or to the extent they request documents or information that are in the public domain and of no greater burden for Plaintiff to obtain.

11. Hetero objects to the Requests to the extent that they call for trade secrets, commercially sensitive materials, or other privileged, confidential, proprietary, or financial information, the release of which is likely to be injurious to Hetero.

12. Hetero objects to the Requests to the extent the documents or things requested constitute confidential and/or proprietary information belonging to third parties with whom Hetero has entered into non-disclosure or confidentiality agreements that prohibit disclosure by Hetero of the third-party’s confidential and/or proprietary information.

13. Hetero objects to Plaintiff’s definitions of “document,” “relates to,” “involving,” “refer or relate to” or “relating to,” and “person” as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, and further to the extent

they seek to impose requirements and discovery obligations on Hetero beyond the scope of discovery permitted by the Federal Rules of Civil Procedure.

14. Hetero objects insofar as the Requests purport to require Hetero to produce documents or things at the same time its written responses are served. Hetero will produce documents at a time and place to be mutually agreed upon by the parties.

15. Hetero objects to the Requests to the extent they seek documents or information that is neither relevant to the subject matter of the present litigation nor reasonably calculated to lead to the discovery of admissible evidence.

16. Hetero objects to Plaintiff's instructions to the extent they require identification of lost, discarded, destroyed, or otherwise unavailable documents or things on the grounds that identifying and describing all such documents would be burdensome, oppressive, and logistically impossible.

17. Hetero objects to Plaintiff's instructions purporting to describe the manner in which Hetero is to produce documents and things. Hetero will produce documents in a format mutually agreed upon by the parties.

18. Hetero reserves the right to supplement these General Objections.

19. These responses are made solely for the purposes of discovery in the present litigation. Nothing herein is intended to waive the following objections, which are expressly reserved: all objections as to competence, relevance, authenticity, propriety, materiality and admissibility of the subject matter of the documents or things produced; all objections as to vagueness, ambiguity, or undue burden; all objections on any ground as to the use of any documents or things provided in response to the Request; all objections on any ground to any Request for further responses to these or other discovery Requests; and any and all other objections

and grounds that would or could require or permit the exclusion of any information, document or statement therein from evidence, all of which objections and grounds are reserved and may be interposed at a hearing in this litigation.

SPECIFIC OBJECTIONS AND RESPONSES

REQUEST FOR PRODUCTION NO. 1

Defendants' ANDA, including all amendments and supplements thereto.

OBJECTIONS AND RESPONSE TO REQUEST NO. 1

Hetero incorporates its General Objections. Hetero objects to this Request to the extent that it has already produced the requested documents to Plaintiff.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 2

Each Document and Thing relating to any and all research, testing, studies, or evaluations referenced in or conducted in association with Defendants' ANDA, or Defendants' decision to submit an ANDA concerning the ANDA Products.

OBJECTIONS AND RESPONSE TO REQUEST NO. 2

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product,

and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will produce non-privileged, responsive documents in its possession, custody, or control related to the research and development concerning ANDA No. 219271 to the extent such documents exist, are relevant, can be located after a reasonable search, and have not already been produced or are not publicly available or already in the possession of Plaintiff.

REQUEST FOR PRODUCTION NO. 3

All communications between Defendants and the FDA concerning the ANDA Product and/or any product containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 3

Hetero incorporates its General Objections. Hetero objects to this Request to the extent that it has already produced the requested documents to Plaintiff.

Subject to and without waiving its general and specific objections, Hetero states that it has and will produce communications between Hetero and FDA relating to its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 4

Each Document and Thing relating to Defendants' ANDA.

OBJECTIONS AND RESPONSE TO REQUEST NO. 4

Hetero incorporates its General Objections. Hetero objects to this Request to the extent that it has already produced the requested documents to Plaintiff.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 5

Each Document and Thing relating to Defendants' Paragraph IV Certification.

OBJECTIONS AND RESPONSE TO REQUEST NO. 5

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 6

Each Document and Thing relating to Defendant's proposed label for the ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 6

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product,

and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 7

Each Document and Thing relating to drafts or versions of any proposed labels and/or package inserts submitted in association with Defendants' ANDA.

OBJECTIONS AND RESPONSE TO REQUEST NO. 7

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 8

Each Document and Thing relating to any and all research, testing, studies, or evaluations referenced in or conducted in association with Defendants' ANDA or Defendants' decision to submit an ANDA concerning the ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 8

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 9

Each Document and Thing relating to Defendants' decision to manufacture, market, advertise to sell, offer for sale, and/or import into the United States the ANDA Product and/or any product containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 9

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any

entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 10

Each Document and Thing relating to Defendants' plan(s) to market, advertise, sell, offer for sale, and/or import the ANDA Product and/or any product containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 10

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 11

Each Document and Thing relating to Defendants' expected sales of the ANDA Product and/or any product containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 11

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 12

Each Document and Thing relating to sales or expected sales by any Person of any product containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 12

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product,

and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 13

Each Document and Thing relating to agreements or communications between Defendants and any other person concerning plans to manufacture, use, import, market, advertise, sell, or offer for sale the ANDA Product and/or any product containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 13

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 14

Each Document and Thing relating to any and all development, research, testing, studies, and/or evaluations conducted, whether scientific or marketing in nature, related to the use and/or sales of products containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 14

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 15

Each Document and Thing relating to any alleged prior art to the '952 patent, including all alleged prior art relied on in Defendants' invalidity contentions.

OBJECTIONS AND RESPONSE TO REQUEST NO. 15

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product,

and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it will produce documents referenced in its invalidity contentions in accordance with the Court's Scheduling Order.

REQUEST FOR PRODUCTION NO. 16

Each Document and Thing relating to manufacturing of the ANDA Product and/or any product containing cyclophosphamide by or on behalf of Defendants.

OBJECTIONS AND RESPONSE TO REQUEST NO. 16

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 17

Each Document and Thing concerning importation of the ANDA Products and/or any product containing cyclophosphamide by or on behalf of the Defendant.

OBJECTIONS AND RESPONSE TO REQUEST NO. 17

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 18

Each Document and Thing considered by Defendant concerning any evaluation of a possibility of manufacturing, marketing, selling and/or importing the ANDA Products and/or any product containing cyclophosphamide.

OBJECTIONS AND RESPONSE TO REQUEST NO. 18

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this

Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 19

Each Document and Thing identified in Defendants' Initial Disclosures made pursuant to Federal Rule of Civil Procedure 26(a)(1).

OBJECTIONS AND RESPONSE TO REQUEST NO. 19

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero will produce non-privileged, responsive documents in its possession, custody, or control to the extent such

documents exist, are relevant, can be located after a reasonable search, and have not already been produced or are not publicly available or already in the possession of Plaintiff.

REQUEST FOR PRODUCTION NO. 20

Each Document and Thing sufficient to disclose Defendants' organizational structures and the names of their employees.

OBJECTIONS AND RESPONSE TO REQUEST NO. 20

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 21

Each Document and Thing relating to the composition of the ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 21

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this

Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 22

Each Document and Thing that relates to any testing, including any analytical, stability, preclinical or clinical testing of Defendants' ANDA Product, including without limitation, any comparison or comparative test with any other cyclophosphamide-containing composition, or placebo.

OBJECTIONS AND RESPONSE TO REQUEST NO. 22

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 23

Each Document and Thing relating to Defendant's decision to include any solvent in Defendants' ANDA Product formulation, including, without limitation, documents that relate to the function, purpose, and/or rationale for the inclusion of any solvent in Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 23

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 24

Each Document and Thing that relates to Defendants' decision to include ethanol, polyethylene glycol, propylene glycol, and/or monothioglycerol in Defendants' ANDA Product, including, without limitation, documents that refer or relate to the function, purpose, and/or

rational for the inclusion of ethanol, polyethylene glycol, propylene glycol, and/or monothioglycerol in Defendant's ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 24

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 25

Each Document and Thing that relates to the stability and/or purity of Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 25

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any

entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 26

Each Document and Thing that relates to the composition of Defendants' ANDA Product, including the amount of API and any other ingredients or impurities.

OBJECTIONS AND RESPONSE TO REQUEST NO. 26

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 27

Each Document and Thing that relates to any type of degradation of cyclophosphamide in Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 27

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 28

Each Document and Thing that relates to the research, development, and/or formulation of Defendants' ANDA Product or any cyclophosphamide-containing composition, including, without limitation, any laboratory notebooks, test data, meeting minutes, developmental reports, and testing protocols.

OBJECTIONS AND RESPONSE TO REQUEST NO. 28

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and

not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 29

Each document and thing that relates to any efforts by, on behalf of, or at the direction of Defendants to combine cyclophosphamide with one or more solvents, during the research and development of Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 29

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product,

and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 30

Each document and thing that relates to any efforts by, on behalf of, or at the direction of Defendants to combine cyclophosphamide with one or more antioxidants, during the research and development of Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 30

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 31

Each Document and Thing that relates to any efforts by, on behalf of, or at the direction of Defendants to combine cyclophosphamide with different amounts of antioxidants, during the research and development of Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 31

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 32

Each Document and Thing that relates to any discussion or comparison of Defendants' ANDA Product and any other cyclophosphamide-containing composition, including, without limitation, the bioequivalence, formulation, pharmacokinetics, and stability of the compositions.

OBJECTIONS AND RESPONSE TO REQUEST NO. 32

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and

not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 33

Each Document and Thing that relates to any inactive ingredients in Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 33

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 34

Each Document and Thing that relates to the manner in which the ethanol in Defendants' ANDA Product contributes to the stability of the product over the shelf life of the product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 34

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 35

Each Document and Thing that relates to the manufacture, synthesis, or preparation of any inactive ingredients in Defendants' ANDA Product.

OBJECTIONS AND RESPONSE TO REQUEST NO. 35

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and

not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero states that it produced a copy of its ANDA No. 219271.

REQUEST FOR PRODUCTION NO. 36

Each Document and Thing that relates to any evaluations or opinions regarding the '952 patent or any patent or patent application that resulted in, or shares a priority claim with, the '952 patent, including any opinion relating to the validity, enforceability, or infringement of those patents and applications.

OBJECTIONS AND RESPONSE TO REQUEST NO. 36

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product,

and/or subject to other applicable protections. Such information and documents will not be produced.

Hetero will not produce documents responsive to this Request.

REQUEST FOR PRODUCTION NO. 37

Each Document and Thing that Defendant's intend to rely on to assert the noninfringement, invalidity, or unenforceability of the '952 patent.

OBJECTIONS AND RESPONSE TO REQUEST NO. 37

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero will produce non-privileged, responsive documents in its possession, custody, or control in accordance with the Scheduling Order to the extent such documents exist, are relevant, can be located after a reasonable search, and have not already been produced or are not publicly available or already in the possession of Plaintiff.

REQUEST FOR PRODUCTION NO. 38

Each Document and Thing concerning the interpretation, construction, scope, or meaning of a claim or any element of any claim of the '952 patent.

OBJECTIONS AND RESPONSE TO REQUEST NO. 38

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero will produce non-privileged, responsive documents in its possession, custody, or control in accordance with the Scheduling Order to the extent such documents exist, are relevant, can be located after a reasonable search, and have not already been produced or are not publicly available or already in the possession of Plaintiff.

REQUEST FOR PRODUCTION NO. 39

Each Document and Thing that relates to what Defendant's contend to be the level of a person of ordinary skill in the area of the '952 patent.

OBJECTIONS AND RESPONSE TO REQUEST NO. 39

Hetero incorporates its General Objections. Hetero, in addition to its General Objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not proportional to the needs of the case. Hetero further objects to this Request to the extent it seeks materials that are not in Hetero's possession, custody, or control. Hetero objects to this Request to the extent that it seeks confidential information belonging to any third party, which may require additional permissions. Hetero will comply with the Local Patent Rules and any entered Protective Order provisions applicable to any third party's confidential materials. Hetero further objects to the extent that this Request seeks information that is privileged, work product, and/or subject to other applicable protections. Such information and documents will not be produced.

Subject to and without waiving its general and specific objections, Hetero will produce non-privileged, responsive documents in its possession, custody, or control in accordance with the Scheduling Order to the extent such documents exist, are relevant, can be located after a reasonable search, and have not already been produced or are not publicly available or already in the possession of Plaintiff.

REQUEST FOR PRODUCTION NO. 40

A 10 g sample of each API batch referenced in Defendants' ANDA, sampled to be well-representative of each batch, and the material safety data sheet and any handling and storage instructions for each sample.

OBJECTIONS AND RESPONSE TO REQUEST NO. 40

Hetero objects to this Request as irrelevant, overly broad, unduly burdensome, disproportionate to the needs of the case, and/or cumulative, as Plaintiff is already in possession of Hetero's ANDA documents, and the infringement inquiry in the ANDA context "is properly

grounded in the ANDA application and the extensive materials typically submitted in its support.” *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000). Hetero further objects to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the case because 10 g is far more than necessary to conduct any and all relevant testing.

Subject to and without waiver of the foregoing objections, Hetero is willing to meet and confer regarding Plaintiff’s need for API, and the appropriate amount to satisfy any legitimate need.

REQUEST FOR PRODUCTION NO. 41

10 samples of Defendants’ ANDA product for each lot referenced in Defendants’ ANDA, and the material safety data sheet and any handling and storage instructions and histories for each sample.

OBJECTIONS AND RESPONSE TO REQUEST NO. 41

Hetero objects to this Request as irrelevant, overly broad, unduly burdensome, disproportionate to the needs of the case, and/or cumulative, as Plaintiff is already in possession of Hetero’s ANDA documents, and the infringement inquiry in the ANDA context “is properly grounded in the ANDA application and the extensive materials typically submitted in its support.” *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000). Hetero further objects to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the case because 10 g is far more than necessary to conduct any and all relevant testing.

Subject to and without waiver of the foregoing objections, Hetero is willing to meet and confer regarding Plaintiff’s need for Hetero’s ANDA Product, and the appropriate amount to satisfy any legitimate need.

Dated: March 5, 2025

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